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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
JOYCE, CATHERINE	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/738,404	THORPE ET AL.	
	Examiner	Art Unit	
	Catherine M. Joyce	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-12,25,29-31,34-39,41,42 and 46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *3-12,25,29-31,34-39,41,42, and 46* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 3-12, 25, 29-31, 34-39, 41, 42 and 46 are pending.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 3, 5-12, 25, 29-31, 34-39, 41, 42 and 46, as drawn to a method of treating cancer by administering an immunoconjugate that comprises a first anti-VEGF antibody, thereby localizing the immunoconjugate to the vasculature of the vascularized solid tumor, classified in class 424, subclass 130.1.

II. Claims 4-12, 25, 29-31, 34-39, 41, 42 and 46, as drawn to a method of treating cancer by administering an immunoconjugate that comprises a first anti-VEGF antibody, thereby localizing the immunoconjugate to the stroma of the vascularized solid tumor, classified in class 424, subclass 130.1.

3. The inventions are distinct, each from the other, because of the following reasons:

The inventions of groups I and II are materially distinct methods. For example, the inventions of Group I are directed to methods of localizing immunoconjugates to the vasculature of tumors whereas the inventions of Group II are directed to methods of localizing immunoconjugates to the stroma of tumors. Searching the inventions I and II together would pose an undue search burden.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or

recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Group I is further subject to election of a single disclosed species.

Claim 5 is generic to a plurality of disclosed patentably distinct species comprising methods of treating cancer. The species are as follows: (a) the first antibody of the immunoconjugate comprises a first variable region that includes an amino acid sequence region having the amino acid sequence of SEQ ID NO:7 (claim 10); (b) the first antibody of the immunoconjugate comprises a first variable region that includes an amino acid sequence region having the amino acid sequence of SEQ ID NO:9 (claim 10). The methods are patentably distinct because they are directed to the use of structurally distinct components.

Claim 31 is generic to a plurality of disclosed patentably distinct species comprising methods of treating cancer. The species are as follows: (a) a second anti-cancer agent is a chemotherapeutic agent; (b) a second anti-cancer agent is a radiotherapeutic agent; (c) a second anti-cancer agent is an anti-angiogenic agent; (d) a second anti-cancer agent is an apoptosis-inducing agent; (e) a second anti-cancer agent is a steroid; (f) a second anti-cancer agent is an antimetabolite; (g) a second anti-cancer agent is an anthracycline; (h) a second anti-cancer agent is a vinca alkaloid; (i) a second anti-cancer agent is an antibiotic; (j) a second anti-cancer agent is a cytokine; (k) a second anti-cancer agent is an alkylating agent; (l) a second anti-cancer agent is a coagulant; (m) a second anti-cancer agent is an anti-tubulin drug (all in claim 34). Claim 35 will be examined only to the extent it reads on the elected species. The methods are patentably distinct because they are directed to the use of structurally distinct components.

If any of (a) chemotherapeutic agent, (c) an anti-angiogenic agent, (h) a vinca alkaloid, or (m) anti-tubulin drug is elected above, the election of a single species in claim 35 is required.

Claim 31 is generic to a plurality of disclosed patentably distinct species comprising methods of treating cancer. The species are as follows: (a) a second anti-cancer agent operatively linked to a first targeting region that binds to an accessible component of a tumor cell; (b) a second anti-cancer agent operatively linked to a first targeting region that binds to an accessible component of a tumor stroma; (c) a second anti-cancer agent operatively linked to a first targeting region that binds to a component of a tumor vasculature or intratumoral vasculature (all claim 36). The methods are patentably distinct because they are directed to the use of functionally distinct components.

Claim 36 is generic to a plurality of disclosed patentably distinct species comprising methods of treating cancer. The species are as follows: (a) a cytotoxic agent (claim 37); (b) a cytostatic agent (claim 37); (c) an anticellular agent (claim 37); (d) an antiangiogenic agent (claim 37); (e) an apoptosis inducing agent (claim 37); (f) an anti-tubulin drug (claim 37); (g) Tissue Factor (claim 38); (h) truncated Tissue Factor (claim 38); (i) a Tissue Factor derivative (claim 38); (j) an antibody or antigen binding fragment thereof that binds to Tissue Factor (claim 38); (k) an antibody or antigen binding fragment thereof that binds to truncated Tissue Factor (claim 38); (l) an antibody or antigen binding fragment thereof that binds to a Tissue Factor derivative (claim 38); (m) a fungus-derived toxin (claim 39); (n) a plant-derived toxin (claim 39); (o) a bacteria-derived toxin (claim 39). The methods are patentably distinct because they are directed to the use of structurally distinct components.

Claim 5 is generic to a plurality of disclosed patentably distinct species comprising methods of treating cancer. The species are as follows: (a) alkaline phosphatase; (b) aryl sulfatase; (c) serratia protease; (d) thermolysin, (e) subtilisin; (f) a carboxypeptidase or D-alanylcarboxypeptidase; (g) a cathespin; (h) β-Galactosidase; (i) neuraminidase; (j) β-lactamase; (k) penicillin amidase; (i) cytosine deaminase (all in claim 41). The methods are patentably distinct because they are directed to the use of structurally distinct components.

Claim 5 is generic to a plurality of disclosed patentably distinct species comprising methods of treating cancer. The species are as follows: (a) a phosphate-containing prodrug; (b) a sulfate containing prodrug; (c) a peptide based prodrug; (d) a D-amino acid modified prodrug, (e) a glycosylated prodrug; (f) a β-lactam containing prodrug; (g) optionally substituted phenoxyacetamide; (h) optionally substituted phenylacetamide-containing prodrug; (i) 5-fluorocytosine. The methods are patentably distinct because they are directed to the use of structurally distinct components.

6. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

7. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 of the other invention.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine M. Joyce whose telephone number is 571-272-3321. The examiner can normally be reached on Monday thru Friday, 10:15 - 6:45. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

Catherine M. Joyce
Examiner
Art Unit 1642